

**REMARKS**

Claims 1 to 3, 5 to 8, 10, 12, 14, 16 to 23, 28, 29, 116, and 117 were pending in this application. Claim 11 was canceled in a previous amendment. Claims 4, 9, 13, 15, 24 to 27, and 30 to 115 were withdrawn from consideration. Claims 1 to 3, 5 to 8, 10, 12, 14, 16 to 23, 28, 29, 116, and 117 have been rejected. Claim 1 has been amended, without conceding to the Examiner's characterization and without prejudice. No new matter has been added to claim 1.

**Withdrawal of Finality of Action**

Applicant respectfully asserts that this action's finality is improper. An action is not properly deemed final when "the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement [IDS]." MPEP § 706.07(a). Claims 1-3, 10, 12, 14, 16-23, 28, 29, 116, and 117 were rejected under 35 U.S.C. § 112, first paragraph, for the first time in the Office Action dated March 29, 2004 ("Rejection A"), for reciting caustic compounds (such as H<sub>2</sub>S and sulfuric acid) at unidentified levels and concentrations. Therefore, Applicant submits that the finality of this present action is improper. Because Rejection A was not raised on the first Office Action dated August 8, 2003, the Examiner allowed Applicant only one opportunity to amend before deeming the action final. Although Claim 1 was amended between the first and second Office Actions to include H<sub>2</sub>S and sulfuric acid, Applicant necessitated no new ground for rejection by this amendment because Claim 11 formerly cited these compounds. Amended Claim 1 merely incorporates Claim 11 as originally filed. Therefore, Applicant asserts that the Examiner added this new rejection of his own accord and not due to necessity from Applicant's amendment of the claims nor an IDS filed, thus, this rejection is new and the office action is improperly labeled final.

An additional justification exists for withdrawal of finality of this action.

Claims 1-3, 10, 14, 16-19, 28, 29, 116, and 117 are rejected under 35 U.S.C. § 102(b) as anticipated by Howard J. Milks, Practical Veterinary Pharmacology, Materia, Medica, and Therapeutics (6<sup>th</sup> ed. 1949) ("Milks") for the first time in the Office Action dated March 29, 2004 ("Rejection B"), for reciting sulfur and sulfur compounds. The Examiner, not Applicant, introduced this new reference. Because Rejection B was not raised on the first Office Action dated August 8, 2003, and is not due to Applicant's IDS or amendments, the Examiner improperly designated this Office Action as final.

Therefore, Applicant submits that the finality of this present action is improper. Applicant respectfully requests, for either or both of the foregoing reasons, that the finality of the present action be withdrawn.

35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-3, 5-8, 10, 12, 14, 16-23, 28, and 29 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner noted that imidazole was used in the claims. Applicant has amended Claim 1 (and therefore all of the other pending claims because they each depend on claim 1) without prejudice and without conceding to the Examiner's characterization, and respectfully asserts that this rejection has been overcome.

35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-3, 10, 12, 14, 16-23, 28, 29, 116, and 117 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant traverses this rejection for at least the following reasons.

Applicant disagrees that the application fails to demonstrate how one would make or use the subject invention. The Examiner rejected claims 1-3, 10, 12, 14, 16-23, 28, 29,

116, and 117 under 35 U.S.C. § 112, first paragraph, for describing the use of compounds such as mercaptans, H<sub>2</sub>S, and sulfuric acid, but failing to describe at what concentrations or levels these compounds would be used. The patent application must include enough information to enable one of ordinary skill in the art to use or make the invention. 35 U.S.C. § 112.

Applicant's invention discloses a composition especially formulated for use on the skin, and one of ordinary skill in the art would know how to use the recited compounds so that dermatologic products are not too caustic. (See Declaration of Bhiku Patel, Ph.D. ("Patel Declaration") attached hereto as Exhibit A, ¶¶ 5 and 6.) Applicant's claimed invention contains components, all of which one skilled in this art would recognize, know the properties of, and be able to combine in such a manner to create a safe, non-caustic compositions without undue experimentation. (Patel Declaration, ¶¶ 7 and 8.) Therefore, no need exists to identify specific concentrations of the components of this invention. Applicant respectfully submits that this rejection should be withdrawn.

Further, the Examiner states, "we believe it is generally known to avoid exposure to the caustic materials." However, the Examiner offers no support for this statement and, therefore, has not met his burden. Applicant invites the Examiner to provide an affidavit under 37C.F.R. § 1.104(d)(2), or other reference, in support of this statement. Without such support, the rejection should be withdrawn.

35 U.S.C. § 102

Suzuki

The Examiner rejected claims 1, 2, 5-8, 10, 11, 14, 17, and 18 under 35 U.S.C. § 102(b) as being anticipated by Suzuki JP 3-002124 ("Suzuki"). Applicant traverses this rejection for at least the reasons set forth in prior responses and the following reasons.

Applicant assumes that, in reciting Claim 11, the Examiner intended to write Claim 12. Claim 11 was canceled in a prior action. If this assumption is erroneous, Applicant requests that the Examiner contact Applicant by telephone to clarify.

The Examiner set forth, in rejecting Claims 1, 2, 5-8, 10, [12], 14, 17, and 18 under 35 U.S.C. § 102(b), that the methods claimed by Applicant are anticipated by Suzuki. However, Suzuki specifically identifies that sulfur alone is traditionally used to treat acne and, because the quality of lotion containing sulfur degrades over time, Suzuki teaches how to prevent this degradation. Suzuki, p. 2, 3. Contrary to the Examiner's conclusions, Applicant asserts that Suzuki *does* identify what conditions the claimed compositions treat because Suzuki specifically identifies sulfur lotions used to treat acne. Suzuki, p. 2, 12. Given that acne is attributed to "an interaction among the hormones, keratin, sebum, and bacteria," and not mites (The Merck Manual 811-814 (17<sup>th</sup> ed. 1999) a copy of which is attached hereto as Exhibit B), one of ordinary skill in the art would not find it obvious to use an acne treatment for mite infestation. Although all skin has some mites, the Examiner has not recited any evidence that mites cause acne or that all skin of acne patients is infested<sup>1</sup> with mites. Applicant respectfully submits that the Examiner's conclusion that Applicant's claims are anticipated by Suzuki is incorrect because the Examiner did not acknowledge or identify the correct teachings of Suzuki and, subsequently, inferred that Suzuki's teachings were extremely broad. Because Applicant claims a method of treating excessive mites, not a method of treating acne or enhancing lotion product quality, Applicant respectfully requests that this rejection be withdrawn.

Additionally, the Examiner stated that the methods claimed by Applicant are anticipated by Suzuki because the Examiner inferred that acne is caused by excessive mites.

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<sup>1</sup> Infestation requires excessive mites, rather than the ordinary amount of mites on adult skin.

Suzuki teaches the use of its composition for the "prevention and treatment of acne." Suzuki, p. 12. There is no teaching in Suzuki that acne patients necessarily have mite infestations. Without such a teaching, no anticipation exists, inherent or otherwise, because Applicant's claimed invention is for treating infestations of mites. The Examiner refused to provide an affidavit under 37 C.F.R. §1.104(d)(2) in support of this inference. Therefore, applicant respectfully requests that rejection be withdrawn.

Harry's

The Examiner rejected Claims 1-3, 10-12<sup>2</sup>, 14, 17, and 18 under 35 U.S.C. § 102(a)<sup>3</sup> as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Harry's. Applicant traverses this rejection for at least the following reasons.

Applicant respectfully disagrees that Claims 1-3, 10, 12, 14, 17, and 18 are anticipated by Harry's under 35 U.S.C. § 102(b) for at least the reasons asserted in prior responses and the following reasons. The Examiner asserted that, because Harry's teaches compositions useful for several skin ailments, Harry's automatically teaches a method of treating excessive mites. Under 35 U.S.C. §102, all of the elements of the claim must be present in one reference for that claim to be anticipated. Although Harry's discusses several sulfur-containing compositions, Harry's specifically identifies these compositions for use in treating acne, oily skin, and sebum secretion. Harry's, p. 558-560. Harry's does not discuss the

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<sup>2</sup> As noted above, claim 11 has been canceled so Applicant will not address that claim's rejection.

<sup>3</sup> After reviewing the prosecution history, Applicant assumes that the Examiner intended to reject Claims 1-3, 10, 12, 14, 17, and 18 under 35 U.S.C. § 102(b), not 35 U.S.C. § 102(a). In the second Office Action, the Examiner cited to 35 U.S.C. § 102(a) and wrote that the "rejection of record is maintained." However, in the prior (first) Office Action, the Examiner cited to 35 U.S.C. § 102(b) in rejecting Claims 1-3, 10-12, 14, 17, and 18. Applicant assumes that this inconsistency is erroneous. If this assumption is incorrect, Applicant requests that the Examiner contact Applicant by telephone to clarify.

condition of excessive skin mites, the treatment of such, or the relationship between excessive mites and these skin disorders. Mite infestation is a separate skin condition from acne, and Harry's only teaches acne, oily skin, and sebum secretion treatments. Applicant submits that Applicant's claims are novel over Harry's because Harry's does not teach Applicant's invention of treating excessive mites. Applicant respectfully asserts that this rejection should be withdrawn.

Applicant also disagrees that Claims 1-3, 10, 12, 14, 17, and 18 are obvious over Harry's under 35 U.S.C. § 103(a). An invention is non-obvious when the invention is novel compared to the subject matter's prior art as a whole. 35 U.S.C. § 103(a). The Examiner inferred that acne, oily skin, and sebum secretion are caused by mites. Mite infestation is a separate skin condition from acne, and Harry's only teaches acne, oily skin, and sebum secretion treatments. Given that acne is attributed to "an interaction among the hormones, keratin, sebum, and bacteria," and not mites (Exhibit B, The Merck Manual, 811-814), one of ordinary skill in the art would not find it obvious to use an acne treatment for mite infestation. Although all skin has some mites, the Examiner has not recited any evidence that mites cause acne, oily skin, or sebum secretion. Therefore, Applicant respectfully asserts that the Examiner's inference is unsubstantiated and, thus, the rejection should be withdrawn.

Bhagwat

Claims 10, 12, 14, 17-24, 26, 28, and 29 were rejected under 35 U.S.C. § 102(e) as being anticipated by Bhagwat U.S. Patent No. 6,429,231 ("Bhagwat"). Applicant believes the Examiner meant "Bhagwat" instead of "Bhagen." If this assumption is incorrect, Applicant requests the Examiner contact Applicant by telephone to clarify. Applicant respectfully traverses the rejection for at least the reasons set forth in prior responses and the following reasons.

Applicant respectfully disagrees that Claims 10, 12, 14, 17-24, 26, 28, and 29 are anticipated by Bhagwat under 35 U.S.C. § 102(e) because the invention in Bhagwat does not teach Applicant's invention. Bhagwat discloses a composition for disorders "due to microbial infection or changes in normal keratinization, epidermal formation or pilosebaceous function, such as acne, psoriasis, seborrhea, rosacea, ingrown hairs and pseudofolliculitis barbae, and hyperpigmented skin, and cutaneous infection." Bhagwat, col. 1, lines 39-43. An infestation of mites is not synonymous with any of these disorders; a patient with any of these disorders does not necessarily have an infestation of mites. See Marks, Histopathology of Rosacea, 100 Arch. Derm., 683-691 (1969) ("Marks") (a copy of which is attached as Exhibit C), and Exhibit B, The Merck Manual. Although all adult skin (even healthy skin) has some mites, the Examiner has not pointed to any evidence that mites cause any of these disorders. Therefore, Bhagwat's methods do not inherently or explicitly anticipate Applicant's invention. Thus, Applicant respectfully submits that this rejection should be withdrawn.

#### Milks

Claims 1-3, 10, 14, 16-19, 28, 29, 116, and 117 were rejected under 35 U.S.C. § 102(b) as being anticipated by Milks. Applicant respectfully traverses the rejection for at least the following reasons.

Applicant respectfully disagrees that Claims 1-3, 10, 14, 16-19, 28, 29, 116, and 117 are anticipated by Milks under 35 U.S.C. § 102(b). Milks specifically teaches that sulfur alone can be used to treat eczema, mange, and ringworm in veterinary medicine. Milks, p. 554. Nothing in Milks would suggest using this composition in human medicine or to treat humans, to which Applicant's invention is directed. Further, Milks does not teach mixtures of sulfur and a sulfur derivative. Instead, Milks discloses compositions with only one sulfur compound. Milks, p. 559. Milks does not anticipate every element of Applicant's claims. Applicant

asserts that Applicant's invention is novel over Milks because Applicant's invention utilizes a composition of sulfur, a sulfur derivative, and a carrier. Because Applicant does not teach using only sulfur as a treatment, Applicant's invention is novel. Because Applicant's invention discloses the benefits of using a composition that is not just sulfur or a sulfur compound, Applicant's invention is novel over Milks. Applicant respectfully asserts that this rejection has been overcome.

35 U.S.C. § 103

Suzuki or Harry's in View of Bonnar, Lin, and Kligman

The Examiner rejected claims 1-3, 5-8, 10, 12, 14, and 16-20 under 35 U.S.C. § 103(a) as being obvious and unpatentable over Suzuki or Harry's in view of Bonnar, Lin (Lin et al, Sulfur Revisited, 18 J. Am. Acad. Dermatol., 553-558 (1988) ("Lin")), and Kligman U.S. Patent No. 4,752,472 ("Kligman"). Applicant traverses this rejection for at least the reasons set forth in the prior responses and the following reasons.

Applicant disagrees with the Examiner that Applicant's invention is obvious in light of the prior art. Applicant, again, notes that neither Suzuki nor Harry's teaches Applicant's claimed invention because neither reference reveals a remedy for mite infestations. The Examiner asserted that Lin teaches Applicant's invention of treating mite infestations with sulfur and sulfacetamide. This is incorrect. In Table III, Lin teaches only that sulfur, not sulfur derivatives, may be useful for "Demodectic eruptions." Lin, p. 555. Lin notes nothing about the use of sulfur and sulfur derivatives (including sodium sulfacetamide) together for Demodex (mites). Table IV discloses no composition for treating mite infestations, and, instead, lists other disorders (acne, dandruff, etc.) having causes not linked to mite infestations. Lin, p. 556. Applicant asserts that if the Examiner believes that excessive mites cause disorders such as acne, then the Examiner must reveal the reference disclosing this causal relationship. The



Examiner has not, through any reference, shown that any disorder described in Harry's or Suzuki is directly caused by mite infestations. Until the Examiner can provide this evidence, the Examiner's conclusion that Suzuki or Harry's discloses Applicant's invention in light of the other references is flawed. The Examiner has refused to provide a declaration under 37 C.F.R. §1.104(d)(2) or a reference and therefore has not met his prima facie burden.

Additionally, Applicant submits that the Examiner's statement that, Kligman when combined Harry's or Suzuki renders Applicant's invention obvious, is incorrect. The Examiner stated that Kligman reveals that Demodex is present in skin disorders treated by the prior art cited. However, Kligman merely discloses that retention products such as bacteria, fungi, and a mite contribute to follicular debris. Kligman, col. 1, lines 30-33. Kligman nowhere teaches or suggests that this debris causes skin disorders, as the Examiner alleged. Therefore, Kligman sheds no light on the causal relationship between excessive mites and skin disorders.

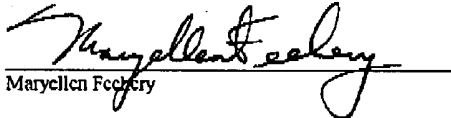
Applicant asserts that the Examiner's use of Bonnar to substantiate the causal relationship between skin disorders and the presence of excessive mites is also not persuasive. The Examiner correctly states that Bonnar discloses that all people have some mites on their skin. However, not all people have infestations of mites. Exhibit C, Marks, p. 683-691. Higher levels of mites might play a role in rosacea's pathogenesis. Bonnar, p. 443, emphasis added. However, not all rosacea patients have excessive mites and, therefore, mite infestation is a condition entirely separate from rosacea. Exhibit C, Marks, p. 690 (stating that evidence of fewer mites on skin afflicted with rosacea substantiates that mites are not significant factor in causing rosacea). Therefore, the use of sulfur in treating skin disorders unrelated to mite infestations in the cited art does not teach or suggest using compositions of sulfur and sulfur derivatives for treating mite infestations. Thus, Applicant's claimed invention is not obvious.

**CONCLUSION**

Applicant respectfully submits that the application is in condition for allowance.

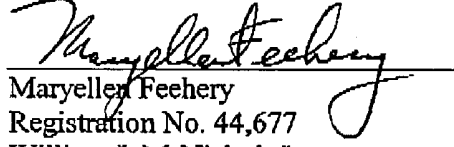
Applicant does not believe any additional fee is required for this Response and Request for Reconsideration, however, in the event any additional fee is required or any overpayment credit is due, the Commissioner is hereby authorized to charge Deposit Account No. 18-0586.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/022,476 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703-872-9306 on the date shown below.

  
Maryellen Feehery

August 3, 2004  
Date of Facsimile Transmission

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